

## **REMARKS**

### **I. Incorporation by Reference of Prior Arguments**

By way of this Response, Applicants re-assert and incorporate by reference their prior arguments before the Office, including those arguments made in the responses submitted on October 8, 2008, March 26, 2008, March 24, 2009, September 10, 2009, and January 15, 2010.

### **III. Claims**

Claims 1-20 are currently pending and stand rejected. By way of this Response, Claims 1 and 11 have been amended. Support for the amendment can be found throughout the specification, including at page 6, lines 1-2 of the application as originally filed. No new matter is presented by way of this amendment.

### **IV. Summary of the March 29, 2010 Office Action**

In the March 29, 2010 Office Action, the Office set forth the following rejections:

- (a) Claims 1, 2, 10, 11, 12, and 20 were rejected under 35 § U.S.C. 103 (a) as being obvious over U.S. Patent No. 6,723,076 (“Strobel”) in view of U.S. Patent No. 5,228,782 (“Imer”);
- (b) Claims 3, 5, 13, and 15 were rejected under 35 § U.S.C. 103 (a) as being obvious over Strobel in view of Imer, further in view of U.S. Patent No. 4,632,267 (“Fowles”);
- (c) Claims 4 and 14 were rejected under 35 § U.S.C. 103 (a) as being obvious over Strobel in view of Imer, in view of Fowles, further in view of U.S. Patent No. 5,494,170 (“Burns”);
- (d) Claims 6-8 and 16-18 were rejected under 35 § U.S.C. 103(a) over Strobel in view of Imer, in view of Fowles, further in view of U.S. Patent No. D456,507 (“LeMarr”); and
- (e) Claims 9 and 19 were rejected under 35 § U.S.C. 103(a) over Strobel in view of Imer, in view of Fowles, further in view of U.S. Patent No. 6,364,143 (“Knierbein”).

**V. The Rejections Under 35 U.S.C. § 103 Should Be Withdrawn.**

The Office rejected independent Claim 1, dependent claims 2 and 10, which depend on independent Claim 1, and independent Claim 11, dependent claims 12 and 20, which depend on independent Claim 11, as obvious under 35 U.S.C. 103 (a) over Strobel in view of Imer. The Office also rejected dependent Claims 3, 5, 13, and 15 which depend from independent Claims 1 and 11, as obvious under 35 U.S.C. § 103 over Strobel in view of Imer and Fowles. The Office additionally rejected dependent Claims 4 and 14, which depend from independent Claims 1 and 11, as obvious under 35 U.S.C. § 103 over Strobel in view of Imer, Fowles, and Burns. The Office further rejected dependent Claims 6 - 8 and 16 - 18, which depend from independent Claims 1 and 11, as obvious under 35 U.S.C. § 103 over Strobel in view of Imer, Fowles, and LeMarr. Finally, the Office rejected dependent Claims 9 and 19, which depend from independent Claims 1 and 11, as obvious under 35 U.S.C. § 103 over Strobel in view of Imer, Fowles, and Knierbein. The Applicants respectfully submit that no *prima facie* case of obviousness has been established because the Office has not demonstrated that the references, regardless if combined, teach or suggest all of the limitations of the claimed invention.

To establish a *prima facie* case of obviousness, three basic criteria must be met. M.P.E.P. § 2143. First, there must be an apparent reason why a person of ordinary skill would have combined the prior art elements in the manner claimed. *KSR Int'l v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007). Second, there must be a reasonable expectation of success. See Exam. Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR Int'l Co. v. Teleflex, Inc.*, 72 Fed. Reg. 57530 (Oct. 10, 2007). Third, the references, when combined, must teach or suggest all the claim limitations or the Office must explain why the shortcomings of the prior art would have been obvious. *Id.* at 57528.

The burden of establishing a *prima facie* case of obviousness lies with the PTO. In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1577-78 (Fed. Cir. 1991). The primary inquiry is: “[w]hether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success ... Both the suggestion and the expectation of success must be found in the prior art, not the applicant’s disclosure.” *In re Dow Chemical*, 837 F.2d 469, 473, 5 U.S.P.Q. 2d 1531 (Fed. Cir. 1988).

Strobel fails to teach or suggest each and every element of independent Claims 1 and 11. Primarily, as the Examiner notes, Strobel fails to teach a connector comprising an elastically deformable injection-molded connecting part with a non-circular cross-section. Furthermore, Strobel fails to teach the present invention of an injection-molded connector part that can be pinched to prevent leakage after filling. Instead, Strobel teaches a clamp that can be used on a delivery tube to ensure that during fluid delivery there is no back flow through the delivery tube back into the bag. (Strobel 5:54-6:6). A person skilled in the art would have no reason to replace the delivery tube of Strobel with an elastically deformable injection-molded connecting part. The delivery tube of Strobel already has sufficient flexibility such that it can be clamped. By contrast, an injection-molded part would normally be sufficiently rigid such that it could not be clamped. The present invention solves this limitation by teaching a method where some or all of the injection-molded connecting part contain a noncircular axial cross shape such that the normally rigid injection-molded part could be pinched. Therefore, because Strobel teaches a delivery tube that is sufficiently flexible such that it could be clamped as designed, there would be no teaching, suggestion, or motivation to modify Strobel with an injection-molded part which could normally not be clamped, absent the present invention's noncircular axial cross shape.

Furthermore, Strobel explicitly teaches away from the present invention. Strobel teaches a method that preserve a bag's sterility when a user withdraws liquids specifically because the user is not able to puncture or insert an object into the bag, which would "destroy[] the sterility of the system." (Strobel 1:47-53). By contrast, the present invention allows a spike to be inserted into at least the connector portion of the bag in order to withdraw fluids. (Appl. at [38]-[39]). Therefore, not only does Strobel teach away from the present invention, but there would be no motivation to combine Strobel with a bag system that allows puncturing or inserting an object into the bag to withdraw liquids, as this contradicts the stated purpose and advantage of Strobel.

The deficiencies of Strobel are not cured by Imer. Imer fails to teach a connector comprising an elastically deformable injection-molded connecting part with a non-circular cross-section which can be pinched to prevent leakage after filling, before a closure part is attached. Imer additionally fails to teach puncturing or inserting an object into a bag to withdraw fluids. By contrast, Imer teaches resealing a flexible sachet by folding the sachet at a 45 degree angle, and then inserting it into a holding slit that has been built into the sachet, rather than pinching it

with a pinching device. (Imer 3:19-26). Notably, Imer teaches constructing the flexible sachet using thin film flexible materials, rather than injection-molded components. (Imer 2:66-68). Injection-molded components are more rigid than thin film materials are, so if the sachet in Imer was constructed using injection-molded components rather than thin film materials, it would not be possible to fold the sachet to seal it. Thus, there would be no motivation to combine Imer with an injection-molded component, as the rigidity provided by the injection-molding would prevent folding in the manner taught in Imer.

Therefore, one of ordinary skill in the art, when reading Strobel in view of Imer would not be taught, suggested, or motivated to develop a connector comprising an elastically deformable injection-molded connecting part with a non-circular cross-section that can be pinched to prevent leakage after filling. Furthermore, there would be no motivation to combine Strobel and Imer, as Strobel contains two mechanisms for sealing its delivery tube, either by using a cap on the end of the tube (Strobel 5:21-5:23) or by clamping the tube (Strobel 5:54-6:6). Therefore, there would be no motivation to combine Strobel with Imer to provide yet another method for sealing the tube through folding it.

Thus, even if Strobel were combinable with Imer, which the Applicants deny, Applicants submit that such a combination fails to teach or suggest all the elements of independent Claims 1 and 11, and dependant Claims 2, 10, 12, and 20. Therefore, the Applicants respectfully request that the rejection of Claims 1, 2, 10, 11, 12, and 20 under 35 U.S.C. § 103(a) be withdrawn. The patentability of independent Claims 1 and 11 also establishes the patentability of dependant Claims 3-9 and 13-19. Accordingly, the Applicants also respectfully request that the rejection of Claims 3-9 and 13-19 under 35 U.S.C. § 103(a) be withdrawn.

### **CONCLUSION**

For at least the foregoing reasons, it is respectfully submitted that Claims 1-20 are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Respectfully submitted,

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